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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MEHTA, ASHWIN D

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/696,600	PETERSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 06 February 2004.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-21 and 23-36 is/are pending in the application.  
 4a) Of the above claim(s) 11-17 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-10, 18-21 and 23-36 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 21 January 2003 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The rejections of claims 1-10, 18, 21, 22, and 26-36 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, are withdrawn in light of the claim amendments or cancellation.

### ***Election/Restrictions***

3. Applicants are reminded that non-elected claims 11-17 require cancellation.

### ***Priority***

4. Applicants have amended the application to claim priority to U.S. Application 09/208,349. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Applicants have amended the first sentence of page 1 of the specification to state that the application claims priority to 09/208,349. However, this sentence must state the relationship to the prior non-provisional application, as discussed above, and that the prior non-provisional application is now abandoned.

***Claim Rejections - 35 USC § 112***

5. Claims 19-20 and 23-25 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed October 7, 2003. Applicants traverse the rejection in the papers filed February 6, 2004. Applicants' arguments have been fully considered but were not found persuasive. Claims 18, 21, and 34-36 are rejected for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 was found indefinite because of the recitation, "as part of a vector." Applicants argue that the claim amendment clarifies the recitation (response, page 15, 5<sup>th</sup> full paragraph). However, the recitation, "A recombination construct comprising a DNA molecule which is part of a vector" renders the claim indefinite for the same reason. It is unclear if the claim is directed to a vector or a recombination construct comprising a DNA molecule. If the claim is directed to a vector, it is suggested that the recitation be re-written as, --A vector comprising a recombination construct comprising a DNA molecule--.

Claims 19, 20, and 24 were and claim 18 is found indefinite because of the recitation, "agronomically significant gene". Applicants direct attention to page 10 of the specification, which provides examples of agronomically significant genes, and argue that the specification teaches the meaning of the recitation (response, paragraph bridging pages 15-16). However, the discussion of agronomically significant genes in the specification pointed to be Applicants starts with the recitation, "For example". It is

unclear what other genes art to be considered “agronomically significant”, besides those recited in the specification.

In claim 36: the recitation, “wherein the recombination construct further comprises a transposon” renders the claim indefinite. It is unclear if the transposon is supposed to be the same as, or in addition to, the Ds element in the recombination construct of the method of claim 2.

6. Claims 8-10 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed October 7, 2003.

Applicants traverse the rejection in the papers filed February 6, 2004. Applicants' arguments have been fully considered but were not found persuasive.

Applicants direct attention to a sentence of the specification that indicates that the Ds element may be within the direct repeats, and argue that one skilled in the art would not have to exercise undue experimentation to practice the invention (response, page 17, 1<sup>st</sup> full paragraph). However, it is not clear what is meant by the Ds element being within the direct repeats. It is also unclear if this is the same as the maize Ds element containing overlapping sequences, as recited in claim 8 (emphasis added). Further, as discussed in the previous Office action, the specification teaches that the homologous recombination occurs between the direct repeats as a result of Ds excision. The specification and the prior art do not teach that homologous recombination occurs in sequences within the Ds

element after the Ds element excises from the DNA molecule where it resided. The specification also does not provide any guidance at all as to how the Ds element is to be situated within, as opposed to between, the direct repeats that are to undergo homologous recombination, and this teaching is also not provided in the prior art. In the absence of further guidance, undue experimentation would be required by one skilled in the art to make these determinations. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claim 1 remains rejected under 35 U.S.C. 102(a) as being anticipated by Shalev et al. (Genetics, July 1997, Vol. 146, pages 1143-1151). This rejection replaces the rejection under 35 U.S.C. 102(b), as Applicants have claimed priority to U.S. Application 09/208,349, now abandoned. Applicants traverse the rejection under 35 U.S.C. 102(b) in the paper filed February 6, 2004. Applicants' arguments have been fully considered as they apply to the current rejection but were not found persuasive.

The claims are broadly drawn towards any method to induce homologous recombination of a nucleotide sequence in a recombination construct in a plant,

comprising introducing a recombination construct to the plant and expressing a transposase within the plant to induce homologous recombination in said construct within said plant; or wherein the recombination construct comprises a maize Ds element and the transposase is of maize origin; or wherein the recombination construct comprises direct repeats proximal to the Ds element; or wherein the transposase is Ac; or wherein the plant is a dicot.

Shalev et al. teach an assay for homologous recombination induced by excision of a transposable element, induced by the maize Ac transposase, in transgenic tobacco plants. Constructs comprising the element were introduced into the plants. Nucleotide sequences on the construct were involved in the homologous recombination event. Recombination induced by transposase expression resulted in the combination of GUS deletion mutants to yield an intact, functional GUS gene (pages 1144-1146).

Applicants resubmit the declaration under 37 CFR 1.131 signed by one of the inventors, Dr. Xiao, which was originally submitted April 16, 2003. The declaration presents exhibits showing a copy of notebook records related to the conception of the construct used to measure recombination of GU-US, and is supposedly dated January 28, 1996. Another notebook entry is also presented, supposedly dated June 9, 1997, which Applicants argue shows a diagram of the construct used in the instant application. Applicants argue that the exhibits pre-date the Shalev article, which was published in July 1997 (response, page 18, 1<sup>st</sup> full paragraph). However, the claim is directed to a method that is not mentioned in the exhibits. The rejection is withdrawn from claims 2-4, 27, and 32, as each and every limitation of the claims is not disclosed by the reference. These

claims require the element to be a Ds element, and the plants taught in the reference that comprise a Ds element do not also express transposase.

***Claim Rejections - 35 USC § 103***

8. Claims 1-7, 24-29, 31, and 32 remain and claims 8-10, 18-21, 23, 30, and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swoboda et al. (EMBO, 1994, Vol. 13, pages 484-489) in view of Shalev et al. (Genetics, July 1997, Vol. 146, pages 1143-1151), Holtorf et al. (Plant Mol. Biol., 1995, Vol. 29, pages 637-646), Hain et al. (Nature, 1993, Vol. 361, pages 153-156), and Fromm et al. (Biotechnology, 1990, vol. 8, pages 833-839), for the reasons of record stated in the Office action mailed October 7, 2003 and . Applicants traverse the rejection in the paper filed February 6, 2004.

Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the Shalev article does not constitute adequate prior art under 35 U.S.C. 102(b) (response, page 19, 1<sup>st</sup> full paragraph). However, despite Applicants' amendment of the instant application to claim priority to U.S. Application 09/208,349, which claims the benefit of provisional application 60/069,057, filed December 10, 1997, Shalev et al. still qualifies as prior art as it was published before this date. Applicants resubmit the declaration under 37 CFR 1.131 signed by one of the inventors, Dr. Xiao, which was originally submitted April 16, 2003. Applicants argue that Exhibit A of the declaration is a copy of notebook records disclosing the construct used to measure recombination GU-US, dated January 28, 1996, and Exhibit B is a copy of notebook records showing a reduction to practice of the construct, dated June 9, 1997. Applicants argue that the Shalev article is not appropriate prior art under 35 U.S.C.

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103(a) because it was published in July 1997 (response, page 18, 1<sup>st</sup> full paragraph).

Exhibit A appears to show steps taken to isolate something termed “GU-US.” However, there is no indication that this is the same as the claimed recombination constructs. The declaration also does not show that the invention as claimed was reduced to practice. The writing on the notebook pages of Exhibits A and B do not mention anything regarding the introduction of any construct into plants, or the claimed methods.

Applicants also argue that the references, individually or combined, do not teach one of ordinary skill in the art to combine elements of the prior art in the manner combined by the inventor. Applicants, as in the response filed June 26, 2003, cite supposed shortcomings of Swoboda et al., Holtorf et al., and Hain et al. individually (response, page 19, 2<sup>nd</sup> full paragraph), despite stating that the combined references do not teach the invention. However, the Examiner maintains that the combined references do teach the claimed invention, as set forth in the rejections of the previous Office actions.

In the Office action mailed October 7, 2003, the Examiner indicated that the Applicants' arguments (in the paper filed March 10, 2003) were found persuasive to overcome the rejection for claims 8-10, 18-23, and 30. This was in response to Applicants' argument that Shalev teaches that GUS reactivation only occurs with Ac in 3'ΔGUS x 5'ΔGUS: Ac crosses, but not with the Ds element, while Applicants' invention is directed to the finding that overlapping foreign gene sequences containing a maize Ds element can be induced to undergo homologous recombination upon introduction of the Ac transposase (response filed April 10, 2003, paragraph bridging pages 13-14). However, this argument is not found persuasive upon further consideration and review of

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Shalev et al. The Ds element used in Shalev et al. was a non-mobile element that was similar to the Ac element but did not express the Ac transposase, and was used in the experiments taught in Shalev et al. as controls in which recombination was not expected to occur, since the Ds element was not expected to excise in the absence of transposase.

Shalev et al. teach that transposase-mediated excision induced the homologous recombination event between the direct repeats, resulting in the formation of a functional gene. Shalev et al. do not teach away from using the Ds element in the presence of the transposase, as argued by Applicants in the response filed March 10, 2003. Rather, Shalev et al. teach that the homologous recombination event requires excision of the element, which requires the transposase.

9. Non-elected claims 11-17 are withdrawn from consideration and claims 1-10, 18-21, and 23-36 are rejected.

#### *Contact Information*

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center

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August 10, 2004



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Art Unit 1638